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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

CHINYERE HARRIS on behalf of herself, and all others similarly situated, and the general public, Plaintiffs, v. GENOMMA LAB USA, INC and DOES 1 to 50, Inclusive, Defendants.	Civil Action No. 1:24-cv-00289-JLT-SAB **AMENDED CONSENT DECREE**

Plaintiff CHINYERE HARRIS ("Plaintiff") and Defendant GENOMMA LAB USA, INC. ("Defendant") (collectively with Plaintiff, the "Parties"), by and through their respective counsel of record, agree to entry of this Amended Consent Decree (the "Decree") without contest, and before any discovery, evidence, or testimony is taken in this case.

I. BACKGROUND

1. Plaintiff filed her class action complaint against Defendant on March 8, 2024 (the "action") alleging Defendant designed, manufactured, marketed, and sold acne treatment products formulated with benzoyl peroxide ("BPO Products"), that degrade to benzene when exposed to normal and expected temperatures use, handing and storage conditions. ECF No. 1. Defendant's BPO Product is Aspexia Acne Treatment Cream formulated with 10% BPO ("Defendant's BPO Product"). This is the only BPO Product made or sold by Defendant.

2. Benzene is a known human carcinogen linked to blood cancers, and other adverse health effects. Drug products contaminated with benzene are deemed misbranded, adulterated, and not legally available for sale in the United States.[1]

3. BPO Products are regulated by the U.S. Federal Drug Administration ("FDA") as "drug products"; thus, Defendant was required to follow the FDA's regulations on labeling requirements, manufacturing practices, and product stability to

[1] *See* 21 U.S.C. § 351(a)(2011); *see also* § 351(b)-(d) (noting that a lack of purity or mixture with another substance also renders drug adulterated).

ensure its BPO Product did not degrade or form contaminants such as benzene. In manufacturing BPO Products, benzene is not used nor allowed in any finished drug product except under a rare exception – where the use of benzene is unavoidable to produce a drug product with a significant therapeutic advantage otherwise not available. In that instance, benzene must be restricted to two parts per million (ppm). Plaintiff alleges Defendant's BPO Product does not meet this rare exception; thus, there should not be any benzene in Defendant's BPO Product. Defendant denies these allegations.

4. This action was filed on March 8, 2024, by Plaintiff on behalf of herself and other consumers similarly situated who used Defendant's BPO Product without knowing they degraded to benzene. The action was filed after the release of independent testing by Valisure, LLC ("Valisure"), which found on-market acne treatment drugs formulated with BPO degrade to benzene when exposed to expected consumer use, handling, and storage conditions and can form levels of benzene up to 800 times the FDA 2 ppm maximum. Valisure's methodology and testing has been peer-reviewed and published in the prestigious epidemiological journal, Environmental Health Perspectives.[2] However, Valisure's methodology and testing has also been

[2] Kucera K, et al., *Benzoyl Peroxide Drug Products Form Benzene*, 3 ENV. HEALTH PERSPECT. 132, 37702-1–3 (Mar. 2024).

criticized by industry manufacturers as deficient, as well as inappropriate for regulatory evaluation under FDA standards.[3]

5. In March 2024, Defendant voluntarily stopped all marketing and production of its BPO Product and does not intend to continue selling it in the future.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

7. **Jurisdiction and Venue.** This Court has jurisdiction over this action and all Parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority. To the extent that this Court lacks personal jurisdiction over any Party, each Party consents to this Court's jurisdiction for any issues related to enforcement and/or adjudication of this Decree and the underlying lawsuit. Venue is proper in the Eastern District of California under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this District. To the extent that venue is not proper, each Party consents to this Court's jurisdiction for any issues related to enforcement and/or adjudication of this Decree and the underlying lawsuit. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

[3] *See, e.g.*, December 5, 2022 FDA Letter to Valisure; July 6, 2021 FDA Inspection Report; July 27, 2021 Valisure Letter to FDA at 1, 3; FDA, *FDA Updates and Press Announcements on NDMA in Zantac (Ranitidine)* (Oct. 2, 2019); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1091-93, 1174-75 (S.D. Fla. 2022); Editorial Board, *The Zantac Scare and Junk Science*, WALL ST. J., Dec. 9, 2022.

DEFINITIONS

8. "Batch" refers to any formulated or finished product not packaged for consumer purchase. "Benzene" refers to the chemical compound, C6H6.

9. "Benzoyl Peroxide" or "BPO" refers to the chemical compound (BzO)2.

10. "BPO Products" refers to any product that contains BPO, whether prescription or over the counter, in any medium, and in any combination, which had BPO in it. This definition also includes any BPO product that may have never been approved for sale.

11. "Inventory BPO Products" refers to any BPO Products in Defendant's possession, custody, or control.

12. "On Market" refers to BPO Products available for retail sale in the United States.

TERMS AND CONDITIONS

7. This Decree shall apply only to Defendant and its agents who are involved with the manufacture, processing, preparing, packing, labeling, holding, marketing, or distribution of its BPO Product, and shall remain in effect until specifically dissolved or vacated by an Order from this Court.

8. **Ceased Marketing and Production of BPO Product.** Defendant voluntarily stopped making its BPO Product in March 2024. Defendant shall not resume marketing and production of its BPO Product in the future unless its manufacturing policies include a requirement that its BPO Product be tested by an

independent third party to ensure it does not degrade to benzene, under normal and expected consumer use. Defendant agrees to provide written notice to the FDA outlining its BPO Product testing protocol before recommencing any BPO Product production in the future. To the extent Defendant retains its BPO Product that has not been sold, Defendant shall not sell such Inventory BPO Product. To the extent applicable, Defendant shall maintain records of the number of Inventory BPO Product, identify where it is stored, and whether/when it has been destroyed, for one year upon the issuance of this Decree.

9. **Limited to No Availability of BPO Product On Market.** Defendant is informed and believes, and therefore represents, that its BPO Product is no longer available or soon to be unavailable On Market, and that primary retailers of Defendant's BPO Product have exhausted, or will soon exhaust, all stock of the BPO Product. Defendant further represents that the BPO Product's market share since 2019 is less than one-twentieth of one percent of all US Acne Products; therefore the current presence of its BPO Product On Market is *de minimis*.

10. **Destruction of BPO Products.** To the extent Defendant locates any BPO Product in its possession, custody, or control, Defendant shall destroy it. Defendant shall bear the costs of destruction and shall be responsible for ensuring the destruction is carried out in a way that complies with all applicable federal and state environmental laws, and any other applicable federal or state law. To the extent that Defendant is under a separate legal obligation to preserve all or a portion of any products, Defendant

shall be allowed to segregate and keep the products for the duration of such preservation obligation.

11. **Preservation of BPO Product Sales Records.** Defendant shall retain all sales, shipping, and distribution records including: the product name; the product size; the batch, lot, and manufacturing codes; and the names of customers, retailers, or distributors to whom the product was shipped, along with quantities shipped. Defendants shall make the records described in this paragraph available to the FDA upon request.

12. **Compliance.** Defendant shall maintain records of all the steps taken above and shall make the records available to the Plaintiff's counsel or the FDA upon request. Defendant shall provide to Plaintiff's counsel an affidavit of compliance with the terms of the Decree within 30 days of its entry. If Defendant fails to comply with any provisions of the Decree, Plaintiff may file a motion for contempt seeking liquidated damages in the amount of $5,000 for each day the Defendant is in violation of the Decree, court costs, and reasonable attorneys' fees should Plaintiff's counsel be deemed a prevailing party.

13. **Not Confidential.** The terms and conditions of this Decree are not confidential and shall be publicly available.

14. **Attorneys' Fees and Court Costs.** The Parties are to bear their own attorneys' fees and costs in this action except in the case of any Decree contempt or enforcement actions.

15. **Dismissal with Prejudice.** Within five (5) calendar days of Plaintiff's receipt of Defendant's affidavit of compliance with the terms of the Decree, Plaintiff will file a Stipulation of Dismissal with Prejudice of the above-captioned action with prejudice pursuant to Federal Rules of Civil Procedure 41(a)(1)(A)(ii).

(Consent of the parties is reflected on the next page._

The undersigned consent to the entry of this Decree.

DATED: October 29, 2024

WISNER BAUM LLP

By: */s/ Stephanie Sherman*

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DATED: October 29, 2024

By: */s/ Ashley D. Bowman (with permission)*

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IT IS SO ORDERED.

Dated: Jennifer L. Thurston
UNITED STATES DISTRICT JUDGE